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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/895,936	07/17/97	WISNEIEWSKI R	17882706

021971
WILSON SONSINI GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO CA 94304-1050

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EXAMINER	
FORD, J	

ART UNIT	PAPER NUMBER
3743	20

DATE MAILED: 09/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No.	Applicant(s)
	08/895,936	Wisneiwski
	Examiner	Art Unit
	Ford	3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 4-18-01

2a)☑ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) 36-40, 44-62, 64-66 and 68 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) 36-40, 44-62, 64-66 and 68 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☑ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: _____

Applicants' response (Paper No. 22) to the notice of non-responsive amendment (Paper No. 21) has been received. Applicants state that pending claims 36-40, 44-52, 55-62, 64, 65 and 68 are all readable on the elected species. Applicants appear to be under the impression that claims 53, 54 and 66 have been canceled or otherwise designated as non-elected. The examiner's file contains no record of any cancellation or withdrawal of claims 53, 54 and 66. In the Examiner's file a total of 68 claims have been presented and of those claims 1-35, 41-43, 63 and 67 have been canceled To expedite prosecution, the Examiner treats those claims (i.e. claims 53, 54 and 66) on the merits along with those claims identified above by Applicants. Claims 36-40, 44-62, 64-66 and 68 are treated on the merits here.

With regard to the journal article, the Examiner specifically asked for the 1992 article by Wisniewski and Wu that was referenced on page 43 of their 1996 DMT publication (in Drug Manufacturing Technology Series Vol. 2) and which is disclosed on page 59 of that publication with a 1992 publication date. The Examiner required the earlier article because, in the course of the interviews (Paper Nos. 17 and 18 in SN 08/895,782), counsel argued that the 1996 DMT article previously submitted as prior art and identified as such on the PTO-1449 form (i.e. the Drug Manufacturing technology Series Vol. 2 publication edited by Avis and Wu) was not prior art as to this series of applications. Moreover, the 1992 article, it now turns out, is much more detailed in its disclosure. Counsel and the Examiner noted that a provisional application (60/037,283) under 119 (e) had been filed on February 4, 1997.

Counsel maintained that the 1996 DMT article was less than a year old and was the inventors' own work and thus did not constitute prior art under any section of 35 USC 102 and hence under 103. The Examiner then required a copy of the 1992 article which clearly constitutes prior art under 102(b)/103 and is materially more detailed as to the structure of the heat transfer system than the 1996 DMT article. In response to that request, applicants (in SN 08/895,782) sent yet another 1996 article (published by Advanstar) however on the first page of the text of that article (see footnote at bottom) it is disclosed that the Advanstar article was previously published in February of 1992.

The Examiner also needs an exact publication date (month and day) for each of the 1996 articles (Advanstar and the Drug Manufacturing Technology Series, Vol. 2) to ascertain their prior art status as to this application. It is noted that both 1996 publications have authorship which differs from the current inventive entity and hence would be prior art under 102(a), (e) or (g) and the case law interpreting "another". If counsel continues to insist the 1996 publications are not prior art, please address in detail his reasons why they are not. Please address some comments to the differing inventive entity *vis-a-vis* the authorship entity, and why they should not be treated as disparate under 35 USC 102(a), (e) or (g) and available under 35 U.S.C. 103.

On pages 2 and 3 of the specification under a section entitled "Description of the Prior Art" applicants appear to disclose that liquids, possibly biopharmaceuticals, have been heated and cooled in containers which have structures comprising "extensions of the container or any

structures in the container". Fins are mentioned specifically but are "typically attached to the container or an internal structure at only one point".

Full disclosure of this prior art is needed. If applicant does not have a publication, a carefully drawn sketch with meaningful legends and explanations is required. Disclosure of what processes (e.g. heating, cooling, freezing etc.) have been performed in this acknowledged prior art described on pages 2 and 3 of the specification is required as well as what fluids (e.g. biopharmaceuticals etc) have been processed in the acknowledged prior art container.

Moreover the 1992 disclosure of Wisniewski and Wu does not disclose how close to the wall of the container the heat transfer fins extended, the dimensions of those fins (length, width, height and thickness), the diameter of the container and the volume of the container. Because applicants are in possession of this information and the examiner has no other reasonable way to obtain it, a requirement under Rule 1.56 is set forth here. Timely submission of this information will permit an orderly examination and will avoid the Board having to require such information under Rule 1.196(d) should an appeal be forthcoming.

Applicant's election of the species of Figure 5 in Paper No. 14 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicants' Figure 5 shows a "spur-tube" type heat exchanger 46 with fins 44 coupled to the outer tube wall of the centrally disposed "spur-tube" type heat exchanger 46. Fins 40 coupled to the wall 42 of the container are positioned such that "portions of fins 40 and fins 44 are in

contact, nearly in contact or can be rotated such that this is the case" (see specification, page 5, lines 18-25). Applicants have presented claims 36-40, 44-62, 64-66 and 68, apparently all of which they feel are readable on the elected species.

Claims 36-40, 44-62, 64-66 and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "thermal bridge" as used in claim 36 of this application is vague. It appears to denote any area where one thermally conditioned surface is in greater proximity to another surface (either itself thermally conditioned or unconditioned) than it is to other surfaces within the device. Is that a correct understanding? If not, why not? If not, what is it? It is submitted that the entire content of fluid in the tank will conduct heat, and that any conditioned structure within the container will conduit heat out of the medium if it is cooler than the medium. The opposite is true for a heated surface. It is also unclear what is meant by "close" in claim 36. How close does it have to be? Neither the specification nor most of the claims defines this clearly (claim 46 being the exception).

The term "biopharmaceutical product" as it is used in this application is ambiguous and hence its use in claim 36 is also the source of ambiguity. In contrast with what may be accepted "biopharmaceutical products" such as a product derived from biological sources that has an intended therapeutic application and whose manufacturing is or will be regulated by pharmaceutical or veterinary regulator agencies (see '132 declarations in Paper No. 17), in the

specification applicants state that the present invention can be used to "freeze and preserve a variety of biopharmaceutical products, including but not limited to proteins, cells, antibodies, medicines, plasma, blood, buffer solutions, viruses, serum, cell fragments, cellular components, and any other biopharmaceutical product."

Many of the purported biopharmaceuticals on applicants' list in the specification are not normally considered biopharmaceutical products by applicants' definition (offered up in the '132 declarations in Paper No. 17) above. For example, buffer solutions are acids or bases-dissolved in water not derived from biological sources nor regulated by FDA to the Examiner's knowledge. Blood, per se, such as is drawn from the general population by the Red Cross would not appear to be a biopharmaceutical by affiants' definition yet it appear on applicants' list. On page 133, col. 1, fourth full paragraph, of the 1992 Wisniewski and Wu prior art (Paper No. 19), it states that "buffer salts" can be components of a biopharmaceutical product but it appears the "buffer salts" are not themselves a biopharmaceutical product. "Medicines" are simply understood to be drugs or other agents used to treat disease or injury. They need not be derived from biological sources. What is vital to this examination is to know with reasonable particularity what chemicals when placed in applicants' tank would infringe the claims. Under applicants' expansive definition of biopharmaceuticals in the specification it would appear that many conventional organic and inorganic solutions (e.g. buffer solutions) would be included - against what affiants Arathoon, Burman, Lawlis and Vetterlein (Paper No. 17) would consider to be the reasonable limits of the word. On the other hand, orange juice recently shown to have measurable effects against certain

forms of cancer, was suggested by counsel to not seriously be considered a biopharmaceutical. The Examiner disagrees. If buffer solutions are considered to be biopharmaceuticals and blood, per se, drawn from the general population is a biopharmaceutical, it doesn't seem reasonable to exclude orange juice. The chances of the FDA regulating "buffer solutions" as a pharmaceutical in the future would be about on par with the chances of the FDA regulating orange juice as a biopharmaceutical in the Examiner's opinion. If the definition now includes orange juice based on new research showing its anticancer properties and possible future regulation by the FDA then applicants' use of the word biopharmaceutical seems to include an ever growing and somewhat amorphous list of chemicals that would be perpetually changing as new research was done to show therapeutic properties to products produced by biological processes such as photosynthesis, fermentation and biological agents such as herbs, roots and compounds which are essentially the products of nature. It is impossible to know which of these will be regulated by the FDA in the future given the vicissitudes of government regulation. The term as it is used in the application is deemed by the Examiner to be one that violates the tenets of 35 U.S.C. 112 in that the metes and bounds of the claims cannot be established with the requisite clarity required by the statute and are subject to change based on *future* FDA actions. The would-be infringer would have no clear way of determining infringing behavior, to put it another way. Infringement would be constantly changing depending on what the FDA decided to regulate as a biopharmaceutical. It is noted that the FDA regulates the handling and composition many food items, but that doesn't transform them into biopharmaceuticals even if those food items have some therapeutic benefit. The

definition offered by the declarants appears to be unworkable in the Examiner's opinion and that offered in the specification ambiguous.

The declarations under Rule '132 by Arathoon, Burman, Lawlis and Vetterlein (see Paper No. 17) all appear to define "biopharmaceutical products" much more narrowly than the expansive definition given in the specification. For example, the Examiner knows of no biologically sourced "buffer solution" which in and of itself is regulated by the FDA. Moreover, if there were such a solution, why would it freeze any differently than a buffer solution not regulated by the FDA nor biologically sourced? It is noted that there is a tremendous variety of "biopharmaceutical products" in applicants' list some of which are very large: cells (e.g. blood etc) whereas others are millions if not billions of times smaller (e.g. viruses or salt ions in a buffer solution). It is submitted that the freezing characteristics of solutions at these two extremes would be extremely different. Blood would probably freeze more in the manner of orange juice or milk given its nearly macroscopic cellular nature whereas virus in a suitable buffer solution or water would freeze in the manner of pure or salty water. Affiants Arathoon, Burman, Lawlis and Vetterlein all state in their conclusions that Cothern, Nakamura and Morrison (disclosing orange juice, solid particles in a liquid carrier and milk, respectively) do not suggest or teach devices or methods useful in processing biopharmaceutical products. Lacking in any of the declarations is any supporting reasons or analysis to show why declarant Arathoon, Burman, Lawlis and Vetterlein hold this opinion common to all of them. None of the affiants have provided any facts to support such a sweeping conclusion. Moreover Applicants' response as well as the

declarations under Rule '132 have failed to reconcile the definition of "biopharmaceutical products" stated in the declarations with the disclosure of the chemicals and blood products, medicines, buffers etc. offered up as examples of "biopharmaceutical products" in the specification. The specification definition of biopharmaceutical products clearly encompasses more chemicals than Affiants' declarations under Rule '132. To the extent that the Rule '132 declarations define the term "biopharmaceutical product" more narrowly than what is discussed in the specification, the declarations serve to heighten the ambiguity of the disclosed and claimed "biopharmaceutical products" and what the limits (metes and bounds) of that terminology is to have as a claim limitation. Moreover, in regard to the cited prior art, nothing in the declarations has addressed why one designing freezing equipment for the chemicals disclosed in the specification would not look to the art of freezing water, orange juice or solids suspended in liquids. The declarations under 37 CFR 1.132 (Paper No. 17) are not convincing for these reasons.

Claims 49-54, 59-62 and 64-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In these enumerated claims applicants appear to be claiming features not found in the elected species of Figure 5. These claims are therefore misdescriptive of the elected species of Figure 5 and are rejected here on that basis. No heat exchange fluid flows in fins 44 or fins 40 in the elected species of Figure 5. The fins 44 and 40 are just made of heat conductive material. No

baffles exist in fins 44 & 40 or in the structure 46 in elected Figure 5. Claims 49-54 do not appear to describe elected Figure 5. No gradient cooling or means to produce it is disclosed in elected Figure 5 nor is any means to control cooling rate disclosed. Similarly, claims 59-61 claim features not disclosed in the species of Figure 5. Finally claims 64-66 set forth features not disclosed in the species of elected Figure 5.

All of these claims are deemed misdescriptive of the elected species of Figure 5 and should therefore be designated as non-elected or amended to be readable on the elected species. If applicants maintain that these claims are descriptive of the elected species of Figure 5, specific citation to the relevant portions of the specification and drawings must accompany applicants' response.

PRIOR ART REJECTIONS

Claims 36-40, 44-62, 64-66 and 68 are rejected under 35 U.S.C. 103(a) as obvious over the 1992 publication by Wisniewski and Wu in view of Kaufman et al (US 3,308,552), Longardner (US 5,220,954) and Richelli (GB 845,576) .

The 1992 Wisniewski and Wu research paper appears to disclose almost every feature of the claimed invention including a jacketed container having "second heat exchange members" (i.e. heat transfer fins in Figure 1) coupled to a "structure" (internal heat transfer coil in Figure 1) immersed in the biopharmaceutical contained within the container.

Missing from Figure 1 of the 1992 Wisniewski and Wu publication is at least one "first heat exchange member" coupled to the interior wall of the container in close spaced proximity to the second heat exchange members to define "a gap between the first heat exchange member and the second heat exchange member" in which gap will be formed a "thermal transfer bridge."

See Figure 1 and the description thereof found on pages 134 and 136. Note page 135 should follow page 136 and was apparently printed out of order. The Examiner did not catch this error when he examined SN 08/895,782.

There is no explicit disclosure of any ice bridge in the 1992 Wisniewski and Wu research publication. The phrase "thermal transfer bridge", however appears much broader than simply an ice bridge. See current specification, page 5, lines 13-16, for apparently inconsistent definition: when the medium is being heated, after being frozen, the ice in the "gap" claimed between the two sets of heat transfer fins 40 and 44 in Figure 5 melts quickest leaving liquid in that "gap", hence it would appear that "thermal transfer bridge" is a much broader term than simply an ice bridge and would include liquids. Applicants disclose two sets of heat transfer fins 40 and 44 in Figure 5. As disclosed on page 14 lines 19-20 of the specification fins sets 40 and 44 can be **in contact or nearly in contact**. By contrast, the 1992 Wisniewski and Wu research paper discloses only fins extending from the heat transfer coil towards the wall of the container though these fins must extend far enough toward the container wall to define "compartments" between the fins (1992 Wisniewski and Wu research paper, page 136, first full paragraph).

Kaufman teaches a tank having finned tubes 11-14, such as shown by Wisniewski and Wu, cooperating with fins 15 along the tank wall to produce, among other effects, improved heat transfer.

Similarly Longardner, Figures 11-13, teaches fins 272 cooperating with fins 264, in contact with alternate fins 264 and in spaced non-contacting relation with intermediate fins 264 (i.e. those fins spaced between fins 264 that are in contact with fins 264 which contact fins 272).

To have used either of the fin configurations shown in Kaufman or the configuration of fins shown in Longardner (Figures 11-13) to have improved heat transfer in the 1992 Wisniewski and Wu prior art would have been obvious to one of ordinary skill in the art.

The thermal bridge of ice will inherently form between the centrally mounted heat transfer fins and the heat transfer fins attached to the interior of the container because they are the closest points to one another and both are actively cooled by circulating cooled silicon oil. Closely spaced cooled surfaces are known by those of skill in the refrigeration art to form ice bridges when a liquid is being frozen into a solid.

As evidence to support the Examiner's statement the closely spaced cooled surfaces will inherently form ice bridges (see MPEP 2112- 2112.02, dealing with inherency, incorporated here by reference) , the reader is referred to Voorhees USP 983,466, page 1, col. 2, line 97- page 2, col. 1, line 5 (Voorhees is not relied upon explicitly here, see MPEP 2131.01, sub-section III), wherein it states:

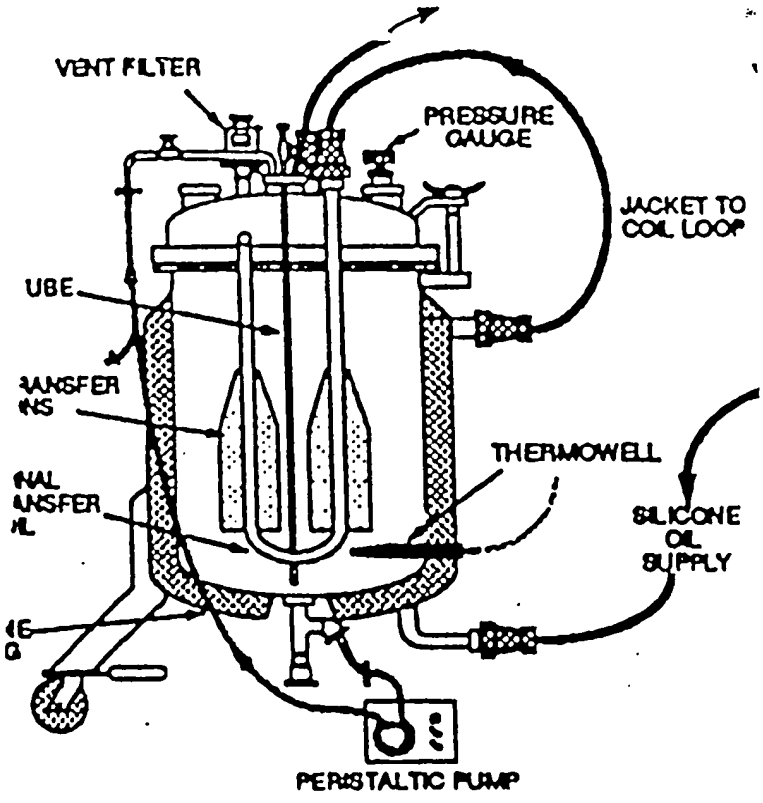
"Whether ice forms in single cakes about several freezing elements or forms in a single cake inclosing a plurality of such elements depends upon the spacing of the several freezing elements from each other. In the first instance of course, ice forms separately about each freezing element, but if these elements be ***close together*** the ice surrounding these elements will soon ***coalesce into a single cake***; and after this has occurred freezing will go on from the surface of the combination cake so formed." (Emphasis supplied).

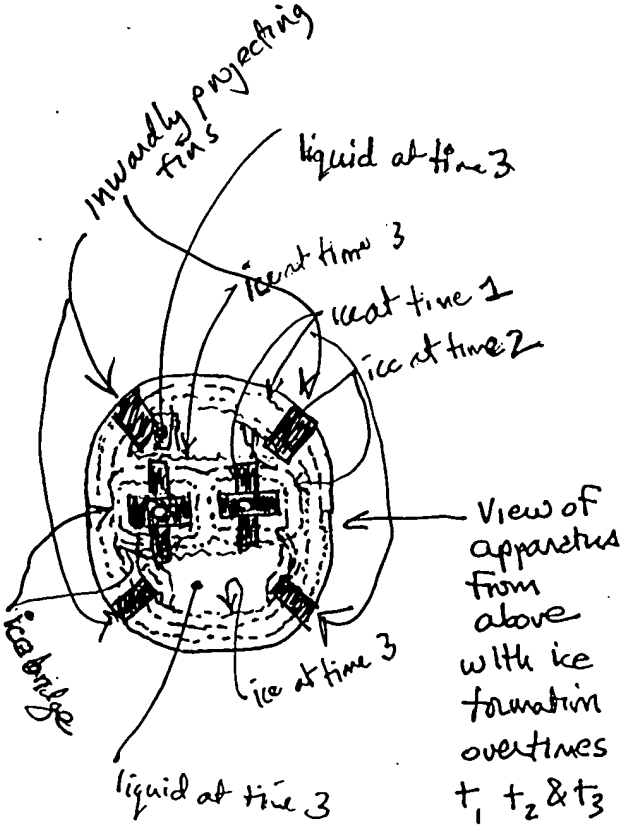
Furthermore, Voorhees, page 2, col. 1, lines 14-21 states:

"I have shown a number of other elements so spaced relatively as to form a single cake 15 of length comparable to cakes formed in plate processes. Of course if the ***freez-ing were continued indefinitely the cakes 12, 13, 14 and 15 would eventually coalesce and freeze to the sides of the tank....***"

It is evident that ice will build up on the heat exchanger and walls of the vessel shown in Figure 1 of 1992 Wisniewski and Wu research paper, during the freezing phase, until they bridge as shown in the diagrams below, a fact that can be established by basic scientific principles. Burroughs et al. USP 3,318,105 illustrates the phenomena. As is clearly seen in Figs. 1A-1C ice builds up evenly on cooled surfaces and even as the top surface freezes the ice coating on the submerged surfaces continues to build up more or less evenly. The same type of analysis is disclosed by Finnegan USP 2,129,572, illustrating that the time required to freeze a substance varies "approximately as the square of the thickness of such substance" with slower freezing generally leading to undesirable concentration effects (what applicants and the 1992 Wisniewski

and Wu research paper refer to as "cryoconcentration"). Finnegan, like the 1992 Wisniewski and Wu research paper, discloses the use of heat exchange fins (projecting inwardly from the exterior wall of the container in the case of Finnegan) to form compartments within the tank to speed the freezing process. Finnegan illustrates using a series of dotted lines how the freezing process progresses over time in various geometries of heat exchange fins. Applying this same science (illustrated by Burroughs and Finnegan) to the system disclosed by 1992 Wisniewski and Wu research paper yield the results illustrated on the immediately below for the system disclosed by the 1992 Wisniewski and Wu research paper in Figure 1.





Even if the 1992 Wisniewski and Wu research paper is deemed not to disclose heat exchanger fins "in close spaced proximity" to fins mounted on the container wall, to have extended the fins in Figure 1 of the 1992 Wisniewski and Wu publication to a point "in close spaced proximity" to the interior surface of a finned container in order to advantageously increase the rate of heat transfer and "divide the tank volume into compartments to decrease the freezing and thawing time and to reduce cryoconcentration effects" (1992 publication, page 136, col. 1, first full paragraph) would have been obvious to one of ordinary skill in the art in view of the respective teachings of the secondary references.

The examiner submits that the fins shown in Figure 1 of the 1992 Wisniewski and Wu publication are already in spaced proximity to the interior wall of the container such that substantially discrete compartments are formed (see page 136, col. 1, first full paragraph) an effect that would be enhanced if the fins were further extended to a point closer to the interior wall of the container and with additional fins projecting from the interior wall of the container.

Moreover, larger fins would increase the amount of surface area for heat transfer, giving an added advantage. On page 136 of the 1992 Wisniewski and Wu publication it states that the "fin's length, thickness and shape were designed to maintain ***efficient heat transfer*** during freezing and thawing." (Emphasis supplied). It is not open to any serious debate that larger, thicker, fins that extend to points closer to the interior wall of the container are more efficient heat

transfer vehicles than smaller, thinner fins that do not extend to points closer to the interior wall of the container.

The 1992 Wisniewski and Wu publication states on page 136: "The heat transfer fins were configured to ***divide the tank into compartments*** to decrease the freezing and thawing time and to reduce cryoconcentration effects. ***Compartmentation*** of the tank is especially effective for maintaining liquid in a static state to minimize cryoconcentration." (Emphasis supplied). The fins are designed to maintain "efficient heat transfer during freezing and thawing" (page 134, col. 2, 1992 Wisniewski and Wu publication). Figure 1 (page 134) of the 1992 Wisniewski and Wu publication clearly shows heat transfer fins extending outwardly from the internal heat transfer coil towards the interior wall of the container. Extending the fins further outwardly to aid in the formation of compartments to minimize cryoconcentration would have been another motivation to one of ordinary skill in the art to make the same modification.

Longardner, in the Figs. 11-13 embodiment, reinforces the teachings of the prior art applied above, teaching fins 272 cooperating with fins 264. The fins 272 are mounted to a cooled/heated container wall 212 and likewise fins 264 are mounted to a centrally disposed heat exchange tube 260. This construction produces increase heat transfer as disclosed by Longardner in col. 8, line 63 - col. 9, line 9 and col. 9, line 67 - col. 10, line 4.

To have used a centrally disposed finned tube such as 260, 264 and tank mounted tabs 272 as taught by Longardner in the system shown in Figure 1 of the 1992 Wisniewski and Wu publication would have been obvious to permit faster heating and/or cooling to take place.

Kaufman, in detail, teaches fins 11a, 11b, 11c and 11d on tubes immersed in a tank as well as fins 15 connected to the inner surface of the tank. In col. 3, lines 46-50, Kaufman discloses a heat transfer function associated with this configuration of elements. To have configured the system shown in Figure 1 of the 1992 Wisniewski and Wu publication with finned tubes in the tank and fins on the inner wall of the tank as taught by Kaufman for the purpose of improving heat exchange would have been obvious.

GB 845,576 teaches similar fins at 23 which would have been obvious to add to the 1992 Wisniewski and Wu publication (Fig. 1) to improve heat transfer. Advanstar publication would have been obvious to permit faster heating and/or cooling to take place.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over the prior art as applied to claim 36 above, and further in view of Brown or Gross.

Brown (Fig. 2) and Gross (Fig. 24) each teach means forming spiral paths on the outside of a tank. To have configured the 1992 Wisniewski and Wu prior art with a spiral path on the outside of the tank would have been obvious to improve heat exchange.

Claims 49-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of the prior art as applied to claim 36 above, and further in view of Cothern (USP 5,535,598).

Cothern in column 7, line 54 - column 8, line 8 teaches various controls for controlling both rate and cooling direction in a freeze container by varying refrigerant flow in the various portions of the device. To the extent that the system disclosed by applicants in Figure 5 can accomplish the functions set forth in claims 49-54, it would have been obvious to have configured

the 1992 Wisniewski and Wu prior art with suitable controls to achieve the same end (those controls being broadly taught by Cothern). Since applicants' own specification is virtually devoid of how these functions are accomplished it must be surmised that obtaining these results must be within the skill of those skilled in the refrigeration art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to John Ford at telephone number (703) 308-2636.

John K. Ford
Primary Examiner

J. FORD:JKF

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.